

R E M A R K S

Claims 1-21 are in the case, with claims 8-14 pending and claims 1-7 and 15-21 withdrawn from consideration at this time. The Examiner and her supervising primary examiner are thanked for the telephonic interview conducted on October 14, 2009.

Rejection under §102(e)

Claims 8-14 stand rejected solely under §102(e), as allegedly anticipated by Arneric (US 2004/0235925). Claim 8, and each of the claims depending therefrom, have been amended to specify that the composition administered in the claimed method consists essentially of a therapeutically effective amount of atomoxetine. Support for this amendment can be found in the Specification at least in the Examples. In view of this amendment, the rejection is believed now to be moot.

In the cited Arneric reference, the invention described involves the treatment of CNS pain and inflammation-related disorders using a *specific combination* of (i) one of three CNS norepinephrine reuptake (neuropathic pain) inhibitors and (ii) the anti-inflammatory agent, cyclooxygenase-2 (COX-2) selective inhibitor or prodrug thereof. (See Arneric at col. 2, para. 0013.) Atomoxetine and the other two CNS norepinephrine reuptake inhibitors (venlafaxen and duloxetine) mentioned in the reference are used and described *solely as norepinephrine reuptake inhibitors (NRIs)*, while the NSAIDs (COX2) are used and described as anti-inflammatory agents. (See, e.g., Arneric at paras. 0009-0011 and 0014.) When fairly read, the cited reference does not mention asthma, and does not anywhere teach or suggest that atomoxetine, in the absence of any of the co-ingredient anti-inflammatory agents, could have any anti-inflammatory effect which could make one consider its use as the principal active ingredient in the treatment of asthma. Moreover, there is no evidence provided in the Office Action suggesting that NSAIDs in anyway are useful agents for the type of inflammation seen in asthma. Applicant believes that the only two types of agents previously found to be useful for the inflammatory component of asthma were corticosteroids and leukotriene inhibitors. See in this connection, for example, the published article, "Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma," National Asthma Education and Prevention Program, NIH Publication No. 02-5074 (June 2003), attached hereto. It should further be noted that atomoxetine shares the same basic mechanism of action in the CNS on norepinephrine as

venlafaxen and duloxetine, but there is no information of record that either of these two drugs has any effect on asthma. See further in this connection the published article, Moultry, M. et al., "The Use of Antidepressants for Chronic Pain," *U.S. Pharmacist* 7/20/2009 (as republished at <http://www.medscape.com>), attached hereto. Moreover, nothing in the cited reference or Office Action would explain how or why one might be motivated to select atomoxetine from amongst the available NRIs, to arrive at a treatment for asthma as claimed.

There simply is nothing of record to suggest that one of skill in the art of asthma treatment could infer from the sole applied reference that atomoxetine alone would or could be considered for use as the principal active ingredient in a treatment of asthma or allergy, without the benefit of Applicant's disclosure.

Accordingly, the cited references cannot support a *prima facie* case of anticipation or obviousness with respect to the presently claimed invention. The case is believed to now be in condition for allowance. Prompt notification to this effect would be sincerely appreciated.

If any matters remain that require further consideration, the Examiner is requested to telephone the undersigned at the number given below so that such matters may be discussed, and if possible, promptly resolved.

Respectfully submitted,

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